

THREADED DEVICE FOR IMPLANTATION BETWEEN VERTEBRAEBackground of the Invention

1 The present application is directed to a threaded
2 interbody device for implantation between a pair of
3 adjacent vertebrae in order to provide support to the
4 vertebrae and/or promote fusion between the vertebrae.

5 In the human spine the pad or disc between vertebrae is
6 sometimes damaged or deteriorates due to age, disease,
7 injury or congenital defect. The vertebrae themselves may
8 also become compressed or otherwise damaged. Because of
9 this, surgery is often utilized to place spacers or
10 interbody devices between the vertebrae which provide proper
11 spacing of the vertebrae and which often are also utilized
12 to promote fusion between the vertebrae. When a device of
13 this type is utilized for purposes of promoting fusion, it
14 is often referred to as a fusion cage or an intervertebral
15 fusion device. When utilized to promote fusion, the
16 interbody devices often are windowed and packed with bone so
17 as to promote growth of the bone between the vertebrae.
18 Sometimes bone is packed between a pair of devices that are
19 placed in close proximity to one another between the

1 vertebrae so as to promote growth of bone and, therefore,
2 fusion between the vertebrae.

3 Interbody devices are typically either generally
4 rectangular in shape or generally cylindrical in shape. The
5 cylindrical devices have an advantage that they can be
6 threadably received between and into the bones themselves.
7 For this purpose, the vertebrae are typically first spaced
8 and then a drill is utilized to create a partial bore in
9 each vertebrae which allows the interbody device to be
10 received between the vertebrae. Because of the space
11 between the bones, the interbody device usually engages the
12 bone's only along an upper surface and a lower surface
13 thereof. When the cage is of a cylindrical threaded type,
14 the upper and lower surfaces are curved and essentially
15 designed to engage the portion of the vertebrae whereat bone
16 is unremoved during boring to create an opening for the
17 device.

18 When interbody devices of this type are used, it is
19 desirable that the device support as much surface of bone as
20 possible to provide strength and reduce the likelihood of
21 subsidence of the device into the bone, especially as part
22 of the bone is spongy by nature. The remainder of the
23 structure mainly functions to support the two surfaces,

1 unless the device is also used as a cage within which to
2 pack bone. Because it is also desirable in such structures
3 to maintain weight and volume as low as possible, in order
4 to make the device more compatible with the body, it is also
5 desirable to make the entire device as small and lightweight
6 as possible, while maintaining strength.

7 Still further, the cylindrical devices are most often
8 threaded in order to bite into the bone of the vertebrae in
9 order to resist inadvertent removal of the devices from
10 between the vertebrae. Therefore the upper and lower
11 surfaces are threaded for this purpose. In the past flat
12 sided segments have been removed and a tool which saddles
13 over the device has been used that slides along the sides
14 thereof to at least partially complete the threads and that
15 can be rotated to allow the device to be screwed between the
16 vertebrae. Consequently, it is desirable to have a side
17 structure that reduces volume, maintains strength and allows
18 for mating engagement with a tool that can both rotate the
19 device and complete the thread during installation.

20 Finally, devices of this type that have sectors in the
21 sidewalls missing are essentially taller than wide. This
22 leads to a potential for instability in that the device can
23 inadvertently rotate 90° during use and partly collapse. In

1 order to avoid this, an additional structure is needed to
2 prevent inadvertent rotation of the device once it is
3 installed.

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5 Summary of the Invention

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7 An interbody or intervertebral spacer device for
8 placement between a pair of spaced but adjacent vertebrae.
9 The device has upper and lower surfaces that are threaded so
10 as to have a helically wound threadform pattern thereon that
11 is discontinuous between the two surfaces, but mateable with
12 a similar threadform on a tool for completion of the thread
13 for use during insertion of the device.

14 The device has an elongate body that extends along an
15 axis of rotation. The upper and lower surfaces of the body
16 are convex and the two side surfaces are concave in shape.
17 That is, a cross-section of the upper surfaces and lower
18 surfaces and the side surfaces have edges which are
19 generally semi-circular in shape, except that the upper and
20 lower surface are convex or bowed outwardly, whereas the
21 side surfaces are concave or bowed inwardly. Preferably the
22 radii of generation of each of the side surfaces, the upper
23 surface and the lower surface are approximately the same.

1 The side surfaces join together the outer edges of the upper
2 and lower surfaces on respective sides of the device. In
3 this manner the device has a profile from the front which
4 approximates a double-headed ax.

5 The devices are utilized in pairs between two adjacent
6 vertebrae. The devices are preferably joined by a bar.
7 Each of the devices has a recess located on the front
8 thereof within which the bar snugly fits such that the bar
9 resists rotation of each device subsequent to installation.
10 This prevents the devices from inadvertently rotating to a
11 non-supporting configuration during use. A set screw joins
12 the bar to each device.

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14 Objects and Advantages of the Invention

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16 Therefore, the objects of the present invention are: to
17 provide an interbody spacer or fusion cage device that is
18 threaded on upper and lower surfaces thereof and can be
19 screwed between a pair of vertebrae in order to support the
20 vertebrae and/or to promote fusion between the vertebrae; to
21 provide such a device having concave arcuate side surfaces
22 that join the upper and lower surfaces on opposite elongate
23 sides of the device; to provide such a device wherein the

1 structure provides strength while reducing volume and
2 weight; to provide such a device wherein the device easily
3 mates with an insertion tool having external threads that
4 align with the threads of the device to allow screwing of
5 the device between a pair of vertebrae; to provide such a
6 device that can be either solid or partly hollow in order to
7 allow packing with bone chips or the like; to provide such a
8 device allowing a relatively close spacing of a pair of
9 devices in side by side relationship; to provide such a
10 device that allows a substantial opening between a pair of
11 devices in side by side relationship to facilitate packing
12 with bone chips and subsequent fusion between the vertebrae
13 associated with the devices; to provide such a device
14 utilized in a pair in conjunction with a bar connecting the
15 pair to resist inadvertent rotation of the devices during
16 use; to provide such a device that includes feathering or
17 reduced thread depth near the front or anterior end of the
18 device to provide an even surface for engagement with a
19 harder bony region near the anterior end of the vertebrae in
20 order to reduce the likelihood of subsidence of the device
21 into the vertebrae after installation; and to provide such a
22 device that is relatively easy to construct, inexpensive to
23 produce and especially well suited for the intended usage

1 thereof.

2 Other objects and advantages of this invention will
3 become apparent from the following description taken in
4 conjunction with the accompanying drawings wherein are set
5 forth, by way of illustration and example, certain
6 embodiments of this invention.

7 The drawings constitute a part of this specification
8 and include exemplary embodiments of the present invention
9 and illustrate various objects and features thereof.

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11 Brief Description of the Drawings

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13 Figure 1 is a perspective view of an interbody device
14 and a bar for linking the interbody device with a second
15 such device in accordance with the present invention.

16 Figure 2 is a front elevational view of the device.

17 Figure 3 is a side elevational view of the device.

18 Figure 4 is a side elevational view of the device on a
19 reduced scale shown positioned between a pair of vertebrae.

20 Figure 5 is a front elevational view on a reduced scale
21 of a pair of the devices joined by the bar and positioned
22 between a pair of vertebrae.

23 Figure 6 is a perspective view of the device mated with

1 a tool for installing the device.

2 Figure 7 is a perspective view of the device being
3 installed with the tool between the vertebrae.

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5 Detailed Description of the Invention

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7 As required, detailed embodiments of the present
8 invention are disclosed herein; however, it is to be
9 understood that the disclosed embodiments are merely
10 exemplary of the invention, which may be embodied in various
11 forms. Therefore, specific structural and functional
12 details disclosed herein are not to be interpreted as
13 limiting, but merely as a basis for the claims and as a
14 representative basis for teaching one skilled in the art to
15 variously employ the present invention in virtually any
16 appropriately detailed structure.

17 The reference numeral 1 generally designates an
18 interbody spacer or device. Normally the device 1 is
19 utilized in pairs and connected with a bar 4 for placement
20 between a pair of adjacent spinal vertebrae 6 and 7.

21 The device 1 has a generally partial cylindrical shape
22 with equal opposed side portions or sectors removed. In
23 particular, the device 1 has a body 10 with an upper surface

1 11 and a lower surface 12. The upper and lower surfaces 11
2 and 12 are semi-cylindrical in shape, elongate and are
3 typically generated from a radii of the same length. The
4 upper and lower surface also have a thread 15 that is wound
5 helically about the device 1 in a pattern that is
6 discontinuous between the upper and lower surfaces 11 and
7 12. The illustrated thread 15 is a V-shaped thread,
8 although other types of thread forms, such as square or step
9 forms, may be utilized in accordance with the invention.

10 As is seen in Figure 3, the thread 15 has a major
11 diameter and minor diameter forming the peaks and valleys of
12 the thread. As the thread approaches the anterior or front
13 end (to the right of Fig. 3) of the device 1 in a region 16
14 the thread depth reduces progressively with each consecutive
15 turn or 360° pass about the device 1. That is, each time
16 the thread 15 passes once around the device 1 in a turn, the
17 thread depth becomes less and the minor diameter of the
18 thread becomes greater.

19 Near the very front of the device 1 the minor thread
20 depth and major thread depth are generally equal so as to
21 produce a generally smooth semi-cylindrical region 17. The
22 semi-cylindrical region 17 provides greater support to an
23 anterior harder bony region 18 of the vertebrae 6 and 7 so

1 as to oppose subsidence during usage. The upper surface 11
2 has opposed parallel edges 20 and 21 and the lower surface
3 12 has similar parallel edges 22 and 23.

4 The body 10 also has a pair of side surfaces 30 and 31.
5 The side surfaces 30 extends between the top surface edge 20
6 and bottom surface edge 22, whereas the side surface 31
7 extends between the top surface edge 21 and bottom surface
8 edge 23. The side surfaces 30 and 31 are curved, arcuate or
9 crescent shaped, as is seen from the front in Fig. 2.
10 Preferably, the side surfaces 30 and 31 each have a radius
11 of generation which is approximately equal. In some
12 embodiments of the invention, the radius of generation of
13 each of the side surfaces 30 and 31 will be equivalent to
14 the radii of generation of the upper surface 10 and lower
15 surface 11, except the side surfaces 30 and 31 will be
16 concave in nature and the upper and lower surfaces 10 and 11
17 are convex. In this manner the side surfaces 30 and 31 are
18 the reverse of the surface that would be generated by either
19 the upper or lower surfaces 10 or 11 being continued with
20 the same arc about the exterior of the device 1. Also, the
21 device has an axis of rotation A. Any plane passing through
22 the device 1 that is perpendicular to the axis A has an
23 intersection with any of the surfaces 10, 11, 30 and 31

1 which is semi-circular.

2 The body 10 also has a generally flat rear surface 39
3 and a front surface 40. The front surface 40 has a
4 vertically centrally located recess 43. The recess 43 has
5 an anterior rectangularly shaped portion 45 and an outer
6 portion 46 which is also centrally rectangular in shape, but
7 has semi-circular upper and lower extensions 48 and 49. A
8 threaded bore 50 passes coaxially through the front surface
9 40 and is centered on the recess 43.

10 The bar 4 is elongate with rounded opposite ends. The
11 bar 4 has a pair of apertures 51 and 52. The bar 4 has a
12 cross-section which is sized and shaped to snugly fit in the
13 recess rectangular portion 45 of each device 1. In this
14 manner, the bar 4, when in the respective recesses 43
15 functions as a lever arm to prevent inadvertent rotation of
16 the devices 1.

17 A pair of set screws 54 are sized and shaped to be
18 received through respective apertures 51 or 52 in the bar 4
19 and subsequently, into and threadably received in respective
20 bores 50 of one of the devices 1. Each set screw 54 has a
21 head 55 that is preferably externally threaded and received
22 in a similar thread in the semi-circular shaped portions 48
23 and 49 of the recess 43. The set screw head 55 also has a

1 coaxially aligned aperture 58 which is sized and shaped to
2 receive a driving tool (not shown) such as an allen wrench.
3 When an allen wrench is to be utilized, the aperture 58 has
4 a hexagonal shaped opening.

5 In use, a pair of devices 1 are positioned between a
6 pair of vertebrae 6 and 7 such as is shown in Figure 5. A
7 tool 60 having side panels 61 and 62 includes a handle 63
8 for turning and is used to insert the devices 1. The side
9 panels 61 and 62 mate with the sides 30 and 31 of each
10 device 1 to complete a cylinder and have external threads 64
11 and 65 that mate with the thread 15 to complete the thread
12 15. The device 1 is placed in the tool 60 in the manner
13 shown in Fig. 6 and then inserted between the vertebrae 6
14 and 7 in the manner shown in Fig. 7. The bar 4 is joined by
15 a pair of set screws 54 to each of the devices 1. Bone
16 chips and the like for promoting growth of bone and fusion
17 between the vertebrae 6 and 7 may be placed between the
18 devices 1, if desired by the surgeon.

19 The devices 1 preferably include no moving or
20 adjustable parts. The devices 1 may be manufactured from
21 biologically inactive materials or from biologically active
22 materials which are compatible with implantation. The
23 devices 1, when formed of biologically inactive materials,

1 are chemically and biologically essentially inert in their
2 implanted environments. Fusion of the vertebrae 6 and 7
3 occurs around the devices 1; however, the devices 1 remain
4 intact after implantation. The biologically inactive
5 materials used for the devices 1 can be divided into
6 metallic materials and non-metallic materials.

7 Metallic biologically inactive materials may include
8 certain alloys of stainless steel, titanium, and tantalum
9 and other alloys which are structurally, chemically, and
10 biologically appropriate. Non-metallic biologically
11 inactive materials for the devices 1 include certain
12 plastics or polymers, organic and inorganic resins,
13 composites, and ceramics. The polymers are preferably non-
14 porous, but may be porous in certain applications. The
15 composites include carbon fiber reinforced materials.
16 Appropriate ceramics are preferably porous and can be of an
17 "open scaffold" type which allow bone fusion growth through
18 the ceramic material itself.

19 The devices 1 alternatively can also be formed from
20 biologically active materials which are normally substituted
21 for, absorbed, or otherwise replaced as bone fusion of the
22 vertebrae 6 and 7 proceeds. The biologically active
23 materials can be either bone-based or non-bone-based. The

1 term bone-based material is used herein to refer to a
2 material which is made from actual bones, bone derivatives,
3 or materials which are chemically bone-like. Bones are
4 typically formed mostly (about 85 percent) of tri-basic
5 calcium phosphate which, in living bone, is called hydroxy-
6 apatite or simply calcium phosphate. In general, the bone
7 is formed by cutting, machining of bone or the like or bone
8 derived material is ground, mixed with a suitable resin or
9 other binder, and cast to shape. Some machining may be
10 performed in final shaping of formed implant devices. The
11 source of bones for such material is preferably the patient
12 who will receive the implant. Other sources may include
13 human cadavers or non-human cadavers.

14 Biologically active, non-bone-based materials
15 appropriate for use in the devices 1 include corals, certain
16 resins and similar materials. The principal constituent of
17 coral is calcium carbonate in a porous form which allows
18 bone fusion growth through the resulting devices 1. The
19 devices 1 can be formed of coral by machining and carving
20 processes or the coral can be rough ground and cemented
21 together in the desired form. The coral material is
22 normally replaced over time by biological processes in the
23 body, as the spinal fusion process occurs.

1 It is to be understood that while certain forms of the
2 present invention have been illustrated and described
3 herein, it is not to be limited to the specific forms or
4 arrangement of parts described and shown.

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